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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,006	10/25/2001	Bruce H. Morimoto	5412/1E887US2	4547

7590 07/11/2005

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EXAMINER	
KISHORE, GOLLAMUDI S	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 07/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/890,006	MORIMOTO ET AL.	
	Examiner	Art Unit	
	Gollamudi S. Kishore, Ph.D	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,8-15,17-20 and 22-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *22,25,26 and 28-31* is/are allowed.

6)☒ Claim(s) *1-3,8-15,17-20,23,24,27 and 32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment and the letter dated 4-21-05 are acknowledged. The new specification is entered in the electronic system.

Claims included in the prosecution are 1-3, 8-15, 17-20 and 22-32. It should be noted that although the wrong specification was entered before, the examined claims were the claims presented by applicant and based on the wrong specification, the rejections, except the 112, 1st paragraph rejection are proper. The 112, 1st paragraph rejection however, is withdrawn.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-3, 8-15, 17-20, 23, 24, 27 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chasalow (5,830, 432)

Chasalow discloses compounds wherein a drug derivatives of phosphocholine and methods of increasing the aqueous solubility of bioactive agent by conjugating them to compounds having phosphocholine moieties. Among the phosphocholines described are hydroxyproline-phosphocholine and tyrosine –phosphocholine. According to

Chasalow, any active agent could be used and those include steroids and aspirin (note the abstract, col. 2, line 25 through col. 4, line 65; examples and claims). . Example 5 in particular shows the attachment of DHEA (steroid) through alcohol linkage to phosphohomocholine.

What are lacking in Chasalow are the examples, wherein of the attachment of instant drugs to the phosphate group of phosphocholine through a linker moiety which is an alkanoyl group. However, It would have been obvious to one of ordinary skill in the art to attach the alcohol functional group of the therapeutic agent to phosphocholine derivative having a carboxylic function (linker) and prepare the prodrugs since Chasalow teaches phosphocholine derivatives with compounds such as hydroxyproline, which have carboxylic functional groups. Such is within the skill of the art. Applicant has not shown any unexpected results modifying the basic teachings of Chasalow by indirectly liking DHEA to phosphocholine, which Chasalow has shown through an example (example 5). The newly presented broad claims falls within the teachings of Chasalow.

This rejection is maintained since the presented claims were searched and the rejection was made based on the claims presented and not on the specification. Applicant provides no additional arguments. The previously presented arguments were addressed by the examiner. To summarize the examiner[s position: - Applicant previously argued that Chasalow is completely silent with respect to using a linker wherein the X moiety is attached to the therapeutic agent via an alcohol functional group. This argument is not found to be persuasive since Chasalow as pointed out

above teaches not just phosphocholine, but also hydroxyproline derivatives of phosphocholine and based on the guidance provided it would be obvious to one of ordinary skill in the art to link this derivative to the alcohol containing therapeutic drug such as DHEA through the carbonyl function. According to instant claim 2, Y is a heterocyclo (C1-8) alkyl and hydroxyproline is a 5-member ring containing heterocyclo compound.

Claim 26 and 31 are allowable.

Claims 22, 25, 26 and 28-31 are allowable if written in and independent form.

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S. Kishore, Ph.D whose telephone number is

(571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

G S Kishore

Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK